

Application No.: 10/801,544
Art Unit: 1634

Request for Reconsideration
Attorney Docket No.: 042187

REMARKS

Claims 1-3, 7 and 8 are pending in the present application and are rejected.

Applicant's Response to Claim Rejections under 35 U.S.C. §112

Claims 1-3, 7 and 8 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action alleges that claims 1, 2 and 7 are confusing as a result of the amendment to recite a “first area,” a “second area,” and a “third area”. Applicant notes that this rejection is despite the fact that Interview Summary dated September 18, 2007 stated that “Mr. Sisson indicated agreement to the use of the term “area” in place of “buffer chamber.””

The apparent confusion appears to be based on an inappropriately narrow definition of the term “area” as being limited to the geometrical definition of length x width. Of course, “area” also is synonymous with words such as “space,” “zone,” “region,” etc. However, the Office Action appears to interpret “area” as being limited to two dimensions. For example, the Office Action states that “[i]t is less than clear as to how one is to fashion an “area” when the “partition” is a pillar array, which is three dimensional, while an area is two dimensional.” February 6, 2008 Office Action, paragraph 5. The Office Action goes on to state that “[i]f one is to fashion an “area,” which is two dimensional and thusly without volume, it is unclear how the biopolymer, which is three-dimensional, can be trapped in two-dimensional area, much less be cause to pass on to a second and/or third area.” February 6, 2008 Office Action, paragraph 6. Finally, the

Office Action states that “[a]cknowledgement is made of the figures depicting a device performing electrophoresis (see Figure 3, below) and that the surface of the device does occupy an “area,” however, such illustrations do not identify “a gel, a pillar array, or a porous filter” as being a first or second area.” February 6, 2008 Office Action, paragraph 7. This final statement is particularly confusing to Applicant, since the claims require that the partition is “a gel, a pillar array or a porous filter.” The claims do not recite that the first or second areas are “a partition, a pillar array or a porous filter.”

In order to address this confusion, Applicant’s representative contacted the Examiner by telephone to have an informal discussion relating to the application. Applicant’s representative inquired as to whether there was another word besides “area” (such as “region,” etc.) which the Examiner felt would improve the definiteness of the claims. In response, the Examiner suggested rewriting the claims to remove the “partitioning...” step. The Examiner also suggested amending the claims to recite “eluting” the biopolymers from the partition.

While Applicant appreciates these suggestions, Applicant respectfully submits that amendment is not necessary in order to overcome the pending rejection based on 35 U.S.C. §112, second paragraph. Thus, Applicant respectfully submits that the claims as written are not indefinite. It is improper to merely select any definition of claim terms which is convenient. While the Office is entitled to the broadest reasonable interpretation of claim terms, “during examination the U.S.P.T.O. must give claims their broadest reasonable interpretation *in light of the specification.*” See MPEP §2111.01 (emphasis added). Accordingly, it is required

that claim terms be given their plain meaning, unless this plain meaning is inconsistent with the specification.

The ordinary and customary meaning of a term may be evidenced by a variety of sources, including “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Phillips v. AWH Corp.*, 415 F.3d at 1314, 75 USPQ2d at 1327. If extrinsic reference sources, such as dictionaries, evidence more than one definition for the term, the intrinsic record must be consulted to identify which of the different possible definitions is most consistent with applicant’s use of the terms. *Brookhill-Wilk I*, 334 F. 3d at 1300, 67 USPQ2d at 1137.

Applicant respectfully submits that the ordinary and customary meaning of the term “area,” in view of the specification, is a definition of space which is synonymous to “zone,” “region,” etc. Additionally, the ordinary and customary term of meaning of the verb “partitioning,” in view of the specification, is the act of dividing a space into parts. Finally, the ordinary and customary meaning of the noun “partition,” in view of the specification, is an object which divides a larger space into two or more parts. Please see the attached dictionary definitions from the *American Heritage Dictionary of the English Language*, 3rd Edition. In view of the above comments, Applicant respectfully submits that the claims as written are sufficiently definite. Favorable reconsideration is respectfully requested.

Applicant's Response to Claim Rejections under 35 U.S.C. §102

Claims 1-3 were rejected under 35 U.S.C. §102(b) as being anticipated by Alam (U.S. Patent No. 5,635,045).

It is the position of the Office Action that Alam discloses the invention as claimed. Alam is directed at an apparatus for, and a method of, electroelution isolation of biomolecules and recovering biomolecules after elution. As illustrated in Figure 1, the system includes a reservoir tank 1 with a separating gel 3 on a horizontal platform 2. The reservoir 1 is filled with buffer 4. Biomolecules are loaded into wells formed in the separating gel 3. Column 5, lines 16-18. The biomolecules are then migrated due to an electrophoretic force between the electrodes 5 and 6. When the biomolecules have migrated partially through the gel 3, a portion of the gel is cut out by a tubular enclosure 7. See Figure 6. This portion of the gel 3 is then placed in the buffer solution. The electrophoretic force causes the biomolecules to migrate until they are accumulated in the membrane 16 of the closure means 8. See Figure 9.

Applicant notes that in the above-referenced telephone discussion, the Examiner raised the possibility that wells of a conventional agarose gel could be interpreted as a “first area,” since the wells are allegedly partitioned from other areas by the gel. Thus, with respect to claim 1, the Examiner may interpret the un-illustrated wells in the separating gel 3 as a “first area,” the separating gel 3 itself as a “partition,” and the reservoir to the right of the separating gel 3 as a “second area.”

However, Applicant respectfully submits that Alam does not disclose or suggest (i) “moving said target biopolymer from within said first area through said partition into said second

area using electrophoresis,” and (ii) “separating said target biopolymer from a buffer in said second area.” In Alam, the biomolecules are moved from wells into the gel 3. Then the gel is cut by a tubular enclosure 7, such that the tubular enclosure 7 holds a gel piece 17. The gel piece 17 is then placed back in the electrophoresis chamber. Then, the biomolecules are run from within the gel piece 17 to accumulate onto a membrane 16. “The semipermeable closure means membrane 16 prevents the migration of protein and nucleic acid out into the buffer tank without hindering the electrophoresis electric field.” Column 6, lines 22-25.

On the other hand, claim 1 requires that the target biopolymers be moved from the first area into the partition and then into the second area. The target biopolymers are then separated from a buffer in the second area. As an example, in Figure 1, target DNA 5 is moved from within solution A 2, into gel 4, and into solution B 3. The target DNA 5 is then separated from the buffer Solution B 3. However, in Alam, the biopolymers are moved from wells (allegedly analogous to a “first area”) into a gel 3 (allegedly analogous to a “partition”). However, the biopolymers are never moved from within the gel 3 into a second area, since the biopolymers are accumulated on a membrane 16. This membrane 16 cannot be a “second area” as set out in the “partitioning” step, since it is not an area of the container partitioned by a partition such as a gel. Rather, the membrane 16 is a separate component.

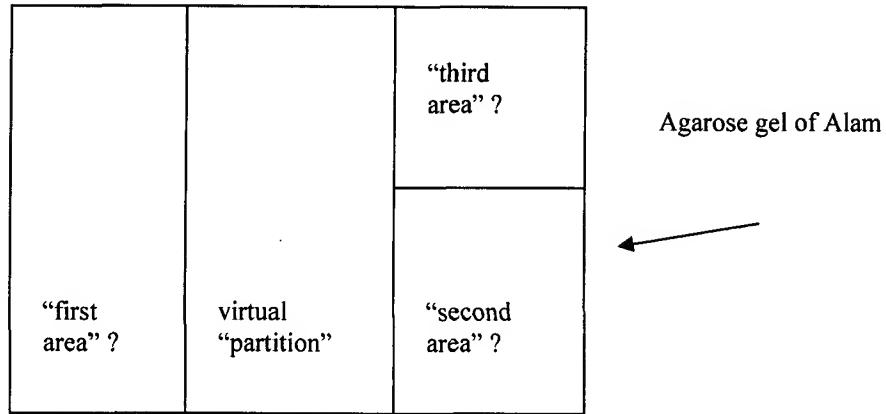
However, even if, *arguendo*, the membrane 16 were interpreted to be a “second area,” Alam does not disclose separating biopolymers from “a buffer” in the membrane. Thus, Alam does not disclose or suggest the step of separating the target biopolymer from a buffer. Rather, in Alam, the biopolymers are merely collected on the membrane 16. Alam does not disclose how

the biopolymers are removed from membrane 16, if at all. Thus, for at least the reasons discussed above, Applicant respectfully submits that Alam does not disclose or suggest the embodiment as recited by claim 1. Favorable reconsideration is respectfully requested.

Applicant now discusses claim 2. First, Applicant respectfully submits that Alam does not disclose or suggest the “partitioning...” step as claimed. Claim 2 requires “partitioning a container into a first area,...a second area,...and a third area...from each other with the use of a partition.” It is unclear how the Office Action regards the container to be partitioned with respect to claim 2. The Office Action states that “the first, second and third “areas” have been construed as being simply different areas of a single gel, where there is no material difference in the composition of the gel exists and where the “partitioning” is virtual, not physical.” February 6, 2008 Office Action, paragraph 10. The Office Action goes on to state that “[s]aid expression has also been construed as encompassing “areas” that have a material difference and which may, or may not, have a physical barrier forming a physical partition.” February 6, 2008 Office Action, paragraph 10.

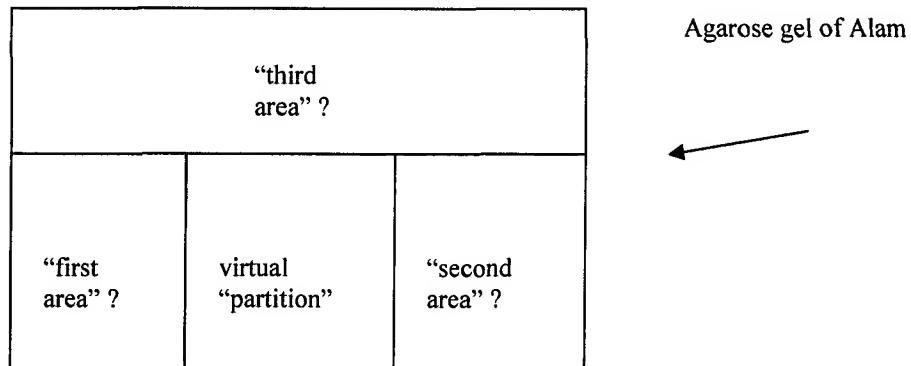
As noted above, claim 2 requires the step of “partitioning a container into a first area,...a second area,...and a third area...from each other with the use of a partition.” In other words, a partition (such as a gel) interposes the first, second and third areas. Even if, *arguendo*, the agarose gel of Alam is interpreted to be “virtually partitioned,” it cannot disclose the recited “partitioning.”

For example, Alam could be “virtually” partitioned in manners such as in the following plan views of the separating gel 3:



In this example, while the first and second area would be virtually partitioned from each other by a virtual partition, and the first and third areas would be virtually partitioned from each other by a virtual partition, the second and third areas would not be partitioned from each other at all. Thus, such a “virtual partitioning” would not meet the requirements of the “partitioning” step of claim 2.

Similarly, the following “virtual” partition could also be made:



In this example, although the first and second areas may be virtually partitioned from each other by a virtual partition, the first and third areas would not be partitioned from each other at all. Likewise, the second and third areas would not be partitioned from each other at all. Thus, such a “virtual partitioning” would not meet the requirements of the “partitioning” step of claim 2. Accordingly, Applicant respectfully submits that Alam cannot disclose or suggest the “partitioning...” step as recited by claim 2.

However, even if, *arguendo*, Alam disclosed a virtual or physical partitioning that meets the requirements of the “partitioning” step, Alam does not disclose or suggest the remaining elements of claim 2. Claim 2 requires that the target biopolymers be moved from the first area into the partition and then from the partition into the third area. Claim 2 also requires that the other biopolymers are moved from the first area through the partition and into the second area. The target biopolymers are then separated from a buffer in the third area. Claim 2 also requires first and second electrophoresis devices. The Office Action fails to clearly identify a second electrophoresis device and a third area.

As an example, in Figure 2, target DNA 5 is moved from within solution A 2, into gel 4 by first electrophoresis device 6/7. Other biopolymers are moved from within solution A 2, into gel 4, and then into solution B 3 by first electrophoresis device 6/7. Target DNA 5 is then moved from within gel 4 into solution C 10 by second electrophoresis device 11/12. The target DNA 5 is then separated from the buffer Solution C 10.

However, in Alam, the biopolymers are moved from wells (allegedly analogous to a “first area”) into a gel 3 (allegedly analogous to a “partition”). However, the biopolymers are never

moved from within the gel 3 into a second area or a third area, since the biopolymers are accumulated on a membrane 16. The Office Action fails to identify specifically what is regarded as the first, second and third areas, and fails to identify where Alam discloses the biopolymers moving into the second and third areas as recited.

This membrane 16 cannot be a “second area” or a “third area” as set out in the “partitioning” step, as it is not an area of the container partitioned by a partition such as a gel. Rather, it is a separate component. However, even if, *arguendo*, the membrane 16 were interpreted to be a “second area,” or even to be a “third area,” Alam does not disclose “a buffer” in the membrane. Thus, Alam does not disclose or suggest the step of separating the target biopolymer from a buffer. Rather, in Alam, the biopolymers are merely collected on the membrane 16. Alam does not disclose how the biopolymers are removed from membrane 16, if at all. Thus, for at least the reasons discussed above, Applicant respectfully submits that Alam does not disclose or suggest the embodiment as recited by claim 2. Furthermore, Applicant respectfully submits that claim 3 is patentable over Alam at least due to its dependency on claim 2. Favorable reconsideration is respectfully requested.

Claim Rejections – 35 U.S.C. §§ 102 and 103

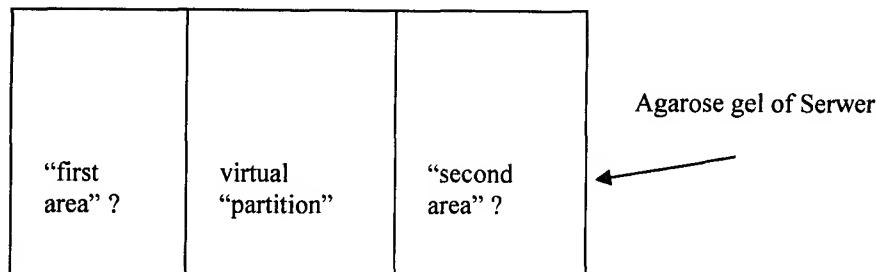
Claims 1-3 were rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being unpatentable over Serwer et al. (U.S. Patent No. 5,009,759).

It is the position of the Office Action that Serwer discloses the invention as claimed. Notably, the Office Action states that “[f]or the purposes of examination, the terms “partition” and “area” have been construed as encompassing not only pillar arrays, and filters but also gels.” February 6, 2008 Office Action, paragraph 18.

Serwer is directed at methods for producing agarose gels having variable pore sizes. Serwer is only directed at an agarose gel and a method of making an agarose gel. Although Serwer discloses separating proteins, DNA, RNA, polysaccharides and the like, Serwer does not disclose or suggest any specific use of the agarose gel.

First, Applicant addresses claim 1. It is noted that the Office Action states that portions of the gel gradient are “deemed to meet the limitation of applicants first and second “partition” as the target biopolymers are removed/separated/portion from the other biopolymers.” February 6, 2008 Office Action, paragraph 19. Applicant respectfully notes that the claims do not recite first and second partitions. Rather, the claims recite first and second areas, which are separated from each other by a partition, which may be a gel, for example. Applicant respectfully requests that future Office Actions, if issued, carefully address the specifically recited claim language.

The Office Action may broadly interpret claim 1 such that it includes “virtual” partitioning, instead of “physical” partitioning. As such, the Office Action appears to be interpreting the Serwer in a manner summarized by the following drawing:

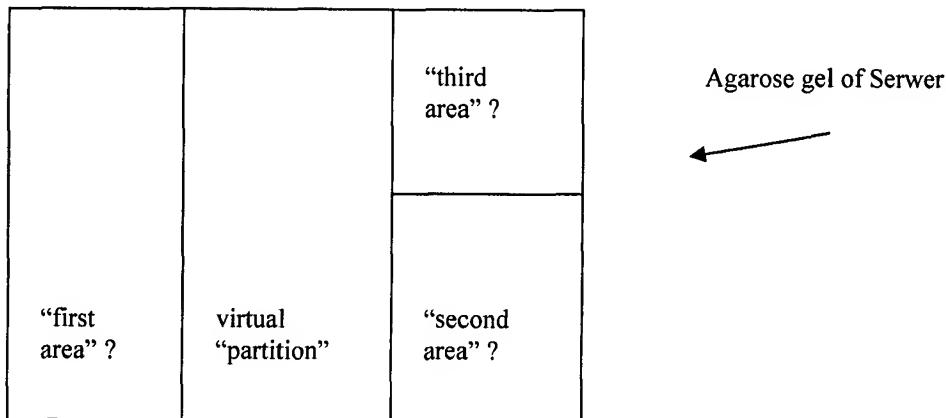


As noted above, Serwer does not disclose or suggest a specific application of the agarose gel. It appears that the Office Action relies upon the broad discussion of separation of proteins, DNA, RNA and polysaccharides. As such, it appear to be the position of the Office Action that the entire gel would be analogous to a “container,” an abstract portion of gel would be a virtual “partition” and portions of the gel which abut such an abstract portion would be “a first area” and “a second area.”

However, in order to anticipate or obviate claim 1, Serwer would also have to disclose or render obvious the step of “separating said target biopolymers from a buffer in said second area.” The Office Action notes that Serwer discloses drying the gel, for example, at column 3, lines 54-58. The Office Action states that this drying of the gel “is deemed to meet the limitation that the biopolymer is separated from buffer.” Even if, *arguendo*, the gel itself were broadly interpreted to be “a buffer in said second area,” Applicant respectfully submits that this disclosure does not anticipate the “separating...” step. Such drying of an agarose gel in itself departs from the premise on which the system of the present invention is based. Applicant respectfully requests

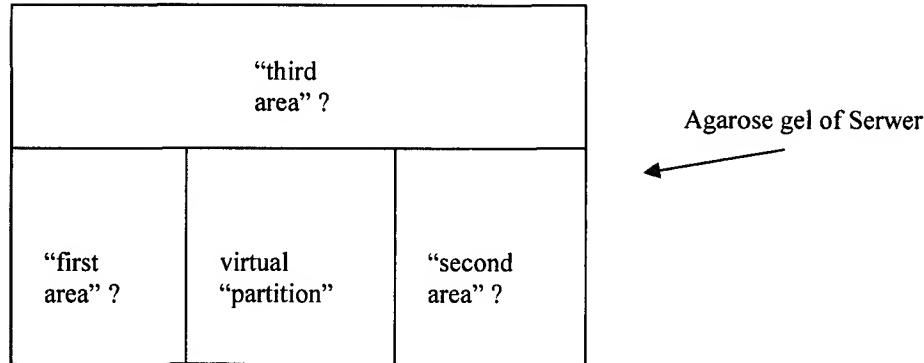
that documentary evidence be provided which supports the position that drying a gel containing a biopolymer amounts to separation of such a biopolymer from such a gel. In the absence of any such evidence, Applicant respectfully submits that Serwer does not disclose or suggest the “separating...” step of claim 1, and thus does not anticipate or obviate claim 1. Favorable reconsideration is respectfully requested.

Applicant now discusses claim 2. Claim 2 requires the step of “partitioning a container into a first area,...a second area,...and a third area...from each other with the use of a partition.” In other words, a partition (such as a gel) interposes the first, second and third areas. Even if Serwer is interpreted to be “virtually partitioned,” it cannot disclose this. For example, Serwer could be “virtually” partitioned in manners such as the following plan views of the gel:



In this example, while the first and second area would be virtually partitioned from each other by a virtual partition, and the first and third areas would be virtually partitioned from each other by a virtual partition, the second and third areas would not be partitioned from each other at all. Thus, such a “virtual partitioning” would not meet the requirements of the “partitioning” step of claim 2.

Similarly, the following “virtual” partition could also be made:



In this example, although the first and second areas would be virtually partitioned from each other by a virtual partition, the first and third areas would not be partitioned from each other at all. Likewise, the second and third areas would not be partitioned from each other at all. Thus, such a “virtual partitioning” would not meet the requirements of the “partitioning” step of claim 2. Accordingly, Applicant respectfully submits that Serwer does not disclose or suggest the “partitioning...” step as recited by claim 2.

Additionally, Serwer does not disclose or suggest the three distinct “moving...” steps as recited by claim 2. Even if, *arguendo*, Serwer disclosed or suggested first, second and third areas partitioned “from each other with the use of a partition,” Serwer does not disclose or suggest any such movement of biopolymers which would conform to the recited “moving...” steps. In other words, even if the Office Action interprets Serwer to be “virtually” partitioned into three areas, Serwer cannot anticipate claim 2 unless it teaches (i) moving “other biopolymers” from a first area through a partition (such as a gel) into a second area, (ii) moving “target biopolymers” from a first area into the partition, and (iii) moving “target biopolymers” from within the partition into

a third area. Serwer does not teach this. Additionally, Serwer does not disclose or suggest using a first electrophoresis device and a second electrophoresis device, as required by claim 2. Finally, as above, Applicant respectfully submits that Serwer does not disclose or suggest the “separating...” step of claim 2. Applicant respectfully submits that claim 3 is patentable over Serwer at least due to its dependency on claim 2. Favorable reconsideration is respectfully requested. Favorable reconsideration is respectfully requested.

Claims 7 and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Alam in view of Straume et al. (U.S. Patent Application Publication No. 2006/0127942).

It is the position of the Office Action that Alam discloses the invention as claimed, with the exception of disclosing the use of magnetic beads. The Office Action relies on Straume to provide this teaching.

Straume is directed at a particle analysis assay for biomolecular quantification. In this assay, DNA probes are attached to two types of beads: magnetically responsive and magnetically non-responsive. The DNA probes then hybridize with target DNA. Next, the magnetically responsive beads are separated from the non-magnetically responsive beads. These magnetically responsive beads may be separated from non-magnetically responsive beads by electrophoresis. See paragraphs [0123]-[0126]. However, these beads must also be electrically charged. See paragraph [0123].

First, Applicant respectfully submits that the combination of Alam and Straume does not disclose or suggest the “partitioning...” step as claimed. Similar to claim 2, discussed above,

claim 7 requires “partitioning a container into a first area,...a second area,...and a third area...from each other with the use of a partition.” It is unclear how the Office Action regards the container to be partitioned with respect to claim 7. It is noted that the Office Action only refers to a “second area,” and does not state where the combination of Alam and Straume discloses a “third area.” To further illustrate this, Applicant notes that the Office Action alleges that the combination of references discloses “separating the target biopolymer (e.g., nucleic acids) from the buffer in the second “area”.” February 6, 2008 Office Action, paragraph 27 (emphasis added). However, claim 7 actually recites “separating the target biopolymer fixed to said magnetic bead from a buffer in said third area” (emphasis added). Again, Applicant respectfully requests that future Office Actions, if issued, carefully address the specifically recited claim language.

Furthermore, Straume only discloses injecting the beads into the buffer of a standard electrophoresis apparatus. This conflicts with the teaching of Alam, which discloses inserting the samples into wells. Furthermore, the combination of Alam and Straume contains no suggestion or disclosure of separating a container into three areas by a partition such as a gel. Rather, the combination of Alam and Straume only appears to disclose a partial separation of a container into two areas. Thus, Applicant respectfully submits that the combination of Alam and Straume does not disclose or suggest the invention as claimed. Favorable reconsideration is respectfully requested.

Application No.: 10/801,544
Art Unit: 1634

Request for Reconsideration
Attorney Docket No.: 042187

Additional Remarks

Additionally, Applicant respectfully requests that a future Office Action, if issued, address each independent claim separately in each rejection, in order to ensure maximum clarity. Applicant also respectfully requests that a future Office Action clearly note where the references are alleged to disclose each claim element. Reference to specific reference numerals or line numbers of the cited art, as well as provision of any illustrations which may be helpful, would be welcomed.

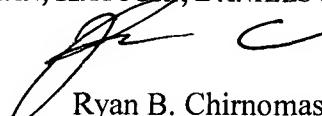
For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

Should the Examiner deem that any further action by applicant would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicant's undersigned attorney.

If this paper is not timely filed, Applicant respectfully petitions for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP



Ryan B. Chirnomas
Attorney for Applicant
Registration No. 56,527
Telephone: (202) 822-1100
Facsimile: (202) 822-1111

RBC/nrp

Enclosures: Dictionary definitions of "area," "partition," and "partitioning"